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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant	:	Bruce C. Johnson	
Serial No.	:	08/615,814	
Filed	:	March 14, 1996	Group Art Unit: 3312
For	:	NASAL DILATOR	Examiner: K. Asher
Docket No.	:	C348.12-0011	

DECLARATION UNDER RULE 132

Commissioner of Patents and Trademarks
Washington, D.C. 20231

Sir:

I, Daniel E. Cohen, hereby declare as follows:

1. I am the Chief Executive Officer of CNS, Inc., a corporation organized and existing under the laws of the State of Delaware.

2. CNS, Inc. entered into a license agreement with Creative Integration & Design, Inc. on January 30, 1992 under which CNS, Inc. was granted rights to make, use and sell products based on or containing the dilator described and claimed in the above-identified patent application filed on behalf of Bruce C. Johnson as inventor and applicant.

3. Having acquired these rights, CNS, Inc. expended development efforts to design a dilator product, and the resulting product developed has therein resilient band springs secured to a flexible strip by deformable adhesive means to extend across the intermediate region of the strip toward each of the end regions at opposite ends thereof to form a unitary, or single body, structure with a further adhesive substance on the ends of the flexible strip on a side opposite the resilient means to permit engaging skin portions of a user such as on the user's nose. As a result, the product developed by CNS, Inc. comes within the scope of at least each of the originally filed independent claims of the above-identified application, and the currently pending independent claims of that application.

4. A Premarket Notification under Section 510(k) of the Federal Food, Drug and Cosmetic Act for the product so developed was submitted to the Food and Drug

Administration of the United States Department of Health and Human Services on March 13, 1992 by CNS, Inc. The Safe Medical Devices Act prevented commercial distribution of that product until the Food and Drug Administration provided written permission to do so, and such permission for sale thereof by CNS, Inc. was obtained with an effective permission date of October 12, 1993.

5. Prior to this latter date, clinical trials of the product developed had been undertaken and samples of that product had been distributed without charge to selected recipients thereof primarily through hospitals and medical clinics by CNS, Inc. However, no publicity information releases or news releases concerning that product were provided to any person or institution by me or CNS, Inc. prior to that date, and no public advertisements of any kind for this product were published by me or CNS, Inc. prior to that date, nor have I or CNS, Inc. paid or otherwise caused others to publish such advertisements prior to that date. Furthermore, neither I nor CNS, Inc. know of any publication of such advertisements prior to that date.

6. CNS, Inc. issued a news release on the above permission date notifying the public of the permission received from the Food and Drug Administration for sales of the product developed, and of the availability of that product. Following this permission date, CNS, Inc. began to accept commercial orders for the product developed thereby, and to meet those orders by making corresponding deliveries of this product to the orderers, or their designees, in return for payments to complete the sales thereof. In addition, employees of CNS, Inc. were interviewed by information media reporters concerning this product as part of their efforts to report news stories in their media.

7. Neither I nor CNS, Inc. published prior to February 11, 1994 any public advertisements concerning the product developed and subsequently sold by CNS, Inc., nor have I or CNS, Inc. paid or otherwise caused others to publish such advertisements prior to that date.

8. Nevertheless, CNS, Inc., following the permission date, received commercial orders as of February 11, 1994 for more than one million units of that product developed thereby, these orders coming primarily from medical clinics, hospitals, retail drugstore chains, and retail drugstore wholesalers, and CNS, Inc. delivered more than one million units of

that product prior to February 11, 1994 pursuant to these orders in return for payments therefor. The product developed by CNS, Inc., the products distributed without charge prior to the permission date, and the products subsequently sold thereafter have all been substantially of the same configuration, and a copy by xerographic reproduction of a sample of that product and of a sample of the box used to package such products is provided in Appendix A based on the sample and box earlier submitted in a declaration by myself in an application parent hereto.

9. Neither I nor CNS, Inc. had any knowledge of any similar unitary or single body dilator operable through adherence to the outer skin of the user under outward stress that was being offered for sale to the public by others as of February 11, 1994.

10. After February 11, 1994, sales and deliveries of the product developed by CNS, Inc. markedly increased as a result of information informally shared by consumers, as a result of publicity, and as a result of advertisements made on behalf of CNS, Inc. By January 1, 1995, CNS, Inc. received orders for the preceding month exceeding one million units for the developed product, and during that preceding month delivered more than one million units of that product in the U. S. Subsequently, during calendar year 1995, CNS, Inc. received orders exceeding one hundred fifty million units of this product developed by them, and delivered nearly that many units in the U. S. In that year. Continuing into 1996, CNS, Inc. has already to date sold and delivered more than that number of units in the U. S. In a further showing of consumers' generally recognizing the advantages of this product developed by CNS, Inc., distributors for CNS, Inc. have to date in 1996 taken delivery from CNS, Inc. a similar number of units of this product for distribution and sale in foreign countries.

11. CNS, Inc. initiated publicity and advertisements for this product developed by them following the permission date that was directed toward medical uses but, unexpectedly, sales of this product related to athletic uses developed. In part, these sales developments are due to showings on television programming of professional athletes using this product developed by CNS, Inc. on their noses during athletic contests, showings which initially were neither solicited nor paid for by either CNS, Inc. or myself.

12. CNS, Inc. and I learned prior to midyear 1995 of the offering for sale and delivery of what I believe to be the first external nasal dilator product offered in competition with the external nasal dilator product developed and sold by CNS, Inc., this competing product appearing to result from an attempt to copy those essentials of the CNS, Inc. product that are commercially necessary as estimated by an independent third party. That third party was, of course, the offerer of the competing product, Bollinger Industries, Inc. of Irving, Texas which sold this competing product under the trademarks AIRFLO and BOLLINGER. This product was formed from a single piece of plastic having adhesive on each end thereof, as well as on the portion between those ends, a sample of which was submitted in a declaration by myself in an application parent hereto. Bollinger Industries, Inc., by such offers for sale of external nasal dilator products, thereby appears to indicate a belief that the essential structural characteristics of an external nasal dilator that have attracted consumers to purchase them in open markets is use of a single piece resilient strip, i.e. a truss, with adhesive at each end thereof which is a structure like that of the CNS, Inc. product except for omitting one resilient band and the fabric strips on either side of the resilient bands used in that product.

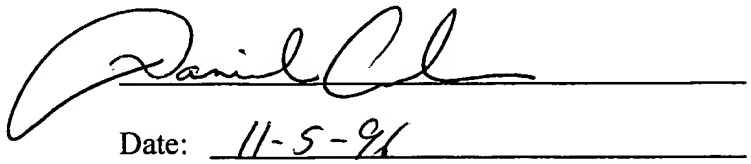
13. At a somewhat later time, CNS, Inc. and I learned of the offering for sale of a second external dilator product in competition with the external nasal dilator product developed and sold by CNS, Inc. This competing product, too, appears to result from an attempt to copy the commercially necessary essentials of the CNS, Inc. product as estimated by MABCO, Inc. of Inglewood, California, another independent third party. The competing product in this second instance was sold under the trademark POWER STRIPS, and again comprises a single piece of plastic. However, this time a fabric layer is provided thereover large enough to extend beyond the edges of such piece of plastic, the piece of plastic and the extended portions of the textile both having an adhesive thereon for engaging the skin of a user's nose. Hence, MABCO, Inc. by such offers for sale, also appears to indicate a belief that the essential structural characteristics of an external nasal dilator that have attracted consumers to purchase them in open markets is a single piece resilient strip, but one covered by a fabric layer in again forming a truss, and with adhesive over the resilient strip and exposed portions of the textile layer for adhering them to a

user's nose. Thus, this second competing product from a second source, MABCO, Inc., has an even greater similarity to the CNS, Inc. product in omitting only one of the fabric strips used in that product, although again omitting one of the resilient bands.

14. In the spring of this year, CNS, Inc. and I learned of the offering for sale of yet another external nasal dilator product to compete with the external nasal dilator product developed and sold by CNS, Inc. This product was been offered to the market by Thrift Drug, Inc. under the mark TREASURY, and has a construction that is even closer to being identical to that of the external nasal dilator product developed and sold by CNS, Inc. in having fabric strips provided on both sides of a resilient band with adhesive for engaging a user's nose adhered to one of those strips. Thus, the external nasal dilator constructions actually sold competively in the United States have steadily become more like that of the CNS, Inc. product to the point of near identicality, with every one of them having used a single body construction exhibiting a normally planar state to which the dilator tends after flexure. Not a one is known to have used the freely available Sawyer reference technology.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further, that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

DANIEL E. COHEN, M.D.



Date: 11-5-96

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AirFlo™
Adhesive Nose Strips
Opens nose.
For any sport.
20 Strips
Included
Pro-Style
Bollinger™
Fitness products for every body
Assorted Colors:
10 Light Beige
5 White
5 Clear

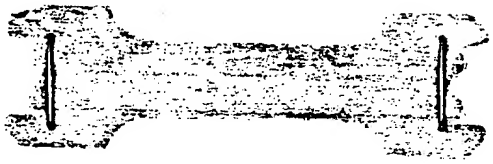
APPENDIX A

Breathe Right® Nasal Strips

Breathe Right® Nasal Strips

PEEL ▼▼ PEEL ▼

U.S.A. Made in U.S.A. Made



Breathe Right®

nasal strips

Improves Nasal Breathing

By Reducing Nasal Airflow Resistance

Drug-free *gently pulls open nasal passages*

10 Med/Lg Nasal Dilators

see back for sizing information

Manufactured by CNS, Inc. • Chanhassen, MN 55317

U.S. and foreign patents pending • Made in the U.S.A.

10 Med/Lg Nasal Dilators

3800-200-006-D